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FOLEY AND LARDNER LLP
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER	
ULM, JOHN D	

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/980,049
Filing Date: November 28, 2001
Appellant(s): POLICKY ET AL.

M. Scott McBride
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 21 April 2006 appealing from the Office action mailed 22 September 2005.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is deficient. 37 CFR 41.37(c)(1)(v) requires the summary of claimed subject matter to include: (1) a concise explanation of the subject matter defined in each of the independent claims involved in the appeal, referring to the specification by page and line number, and to the drawing, if any, by reference characters and (2) for each independent claim involved in the appeal and for each dependent claim argued separately, every means plus function and step plus function as permitted by 35 U.S.C. 112, sixth paragraph, must be identified and the structure, material, or acts described in the specification as corresponding to each claimed function must be set forth with

reference to the specification by page and line number, and to the drawing, if any, by reference characters.

The brief is deficient because the text cited therein as being from the instant specification in support of the claimed subject matter not properly identified and is presented out of context. That summary refers to, for example, "paragraph (0004) the specification". The paragraphs of the instant specification are not numbered.

Further, the text referred to does not state that "GCPRs (G-coupled protein receptors) include receptors for. . .lipid mediators of inflammation (e.g., . . .leukotrienes)". The text referred to is located in the first full paragraph on page 2 of the instant specification, in the section titled "**BACKGROUND OF THE INVENTION**", and it actually states that "GPCRs include receptors for sensory signal mediators (e.g., light and olfactory stimulatory molecules; adenosine, γ-aminobutyric acid (GABA), hepatocyte growth factor, melanocortins, neuropeptide Y, opioid peptides, opsins, somatostatin, tachykinins, vasoactive intestinal polypeptide family, and vasopressin; biogenic amines (e.g., dopamine, epinephrine and norepinephrine, histamine, glutamate (metabotropic effect), acetylcholine (muscarinic effect), and serotonin); chemokines; lipid mediators of inflammation (e.g., prostaglandins and prostanoids, platelet activating factor, and leukotrienes); and peptide hormones (e.g., bombesin, bradykinin, calcitonin, C5a anaphylatoxin, endothelin, follicle-stimululating hormone (FSH), gonadotropic-releasing hormone (GnRH), neurokinin, and thyrotropin-releasing hormone (TRH), and oxytocin))". Nowhere does that text

expressly state or imply that the claimed invention specifically involves a protein having leukotriene receptor activity.

Table 2 on page 81 of the instant specification, when considered in light of the text in the paragraph bridging pages 25 and 26 of the instant specification, **does** clearly teach that the amino acid sequence from the GenBank data base that is most closely related to the amino acid sequence presented in SEQ ID NO:1 of the instant application belongs to a known leukotriene receptor and that the similarities between those sequences, which is not disclosed, is not the result of random chance.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

TAKASAKI et al. "The Molecular Characterization and Tissue Distribution of the Human Cysteinyl Leukotriene CysLT2 Receptor" 02 August 2000, Biochemical and Biophysical Research Communications Vol. 274, no.2 (02 August 2000), pp.316-322

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

>>1 Claims 1 to 7, 9, 1 1 , 16, 17, 19, 22, .26 and 57 to 61 are rejected under 35 U.S.C. § 101 because they are drawn to an invention with no apparent or disclosed specific and substantial credible utility. The instant application has provided a

description of an isolated DNA encoding a putative G protein-coupled receptor protein identified therein as "GCREC-1", and the protein encoded thereby. The instant application does not disclose a credible biological role of this protein or its significance, beyond the fact that it is structurally related to proteins which are known in the art to be members of the G protein-coupled receptor family. The "BACKGROUND" section of the instant specification indicates that different members of the G protein-coupled receptor family receptor family bind to a variety of different chemical compounds that mediate significantly different physiological processes in different types of cells. The instant specification does not expressly identify any ligand for a receptor of the instant invention nor does it identify a specific physiological process that one could reasonably associate with that receptor in light of the evidence of record. To be patentable, an invention must be useful in currently available form. Because the instant specification does not disclose the identity of at least one ligand for a receptor of the instant invention or provide a reasonable basis to support a conclusion that this protein is involved in at least one specific physiological process which one would wish to modulate for clinical effect, the claimed nucleic acid encoding that protein is not useful without further research and inventive contribution.

It is clear from the instant specification that a protein comprising the amino acid sequence presented in SEQ ID NO:1 of the instant application is what is termed an "orphan G protein-coupled receptor" in the art. This is a protein whose cDNA has been isolated because of its similarity to known proteins. There is little doubt that, after complete characterization, this protein and a polynucleotide encoding it may be found to

have a specific and substantial credible utility. This further characterization, however, is part of the act of invention and until it has been undertaken Applicant's claimed invention is incomplete. The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. The court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", " [u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", " [i]t is not a reward for the search, but compensation for its successful conclusion."

The instant claims are drawn to an isolated polynucleotide encoding a protein of as yet undetermined function or biological significance and the protein encoded thereby. There is no evidence of record that would support a conclusion the a protein of the instant invention is causally associated with any one or more of the plurality of disorders that are listed on pages 38 to 40, 53 and 54 of the instant specification. Until some actual and specific significance can be attributed to a protein comprising the amino acid

sequence presented in SEQ ID NO:1 of the instant application, or the gene encoding it, the instant invention is incomplete. The protein encoded by a DNA of the instant invention is a compound known to be structurally analogous to proteins which are known in the art as G protein-coupled receptors. In the absence of a knowledge of the natural ligands or biological significance of this protein, there is no immediately obvious patentable use for it. To employ a nucleic acid or protein of the instant invention in the identification of substances which inhibit or induce its activity or expression is clearly to use it as the object of further research which has been determined by the courts to be a utility which, alone, does not support patentability. Since the instant specification does not disclose a credible "real world" use for to a protein comprising the amino acid sequence presented in SEQ ID NO:1 then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

>>2 Claims 1 to 7, 9, 11, 16, 17, 19, 22, 26 and 57 to 61 are rejected under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to use the instant invention for those reasons given above with regard to the rejection of these claims under 35 U.S.C. § 101.

>>3 Claims 1 to 7, 9, 11, 16, 17, 19, 22, 26 and 57 to 61 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant application as filed did not provide a written description of a polypeptide having the amino acid sequence presented in SEQ ID NO:1 and "cysteinyl

leukotriene receptor activity". In fact, the phrase "cysteinyl leukotriene receptor activity" is without support in the instant application as filed and a relationship between this activity and SEQ ID NO:1 is a new inventive concept.

>>4 Claims 1 to 7, 9, 11, 13, 15 to 17, 19, 22 and 26 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by the Takasaki et al. publication (B.B.R.C. 274(2):316-322, 02 Aug. 2000). Takasaki et al. provided a written description of the claimed invention. The amino acid sequence identified as "PSECO146" in Figure 1 of the Takasaki et al. publication is identical to the amino acid sequence presented in SEQ ID NO:1 of the instant application. Applicant is advised that the instant application can only receive benefit under 35 U.S.C. § 119(e) from an earlier application which meets the requirements of 35 U.S.C. § 112, first paragraph, with respect to the now claimed invention. Because the instant application does not meet the requirements of 35 U.S.C. § 112, first paragraph, for those reasons given above and it is a divisional of application Serial Number 60/193,051, the prior application also does not meet those requirements and, therefore, is unavailable under 35 U.S.C. § 119(e).

(10) Response to Argument

Appellant has traversed the rejections of claims 1 to 7, 9, 11, 16, 17, 19, 22, 26 and 57 to 61 under 35 U.S.C. § 101 for lack of utility, under 35 U.S.C. § 112, first paragraph, as being based upon a specification that fails to adequately teach how to use the instant invention and under 35 U.S.C. § 112, first paragraph, as lacking an adequate written description (new matter) on the premise that the objections and rejections are based on the contention that the present application and its priority

application (U.S. provisional application no. 60/199,084) do not explicitly disclose that the polypeptide of SEQ ID NO:1 is a human G-protein Coupled Receptor for cysteinyl leukotrienes. Actually, the instant rejections for lack of utility and lack of enablement are based upon the position that the specification does not disclose a specific and substantial utility for the claimed invention. Only the rejection of these claims for lack of written description because they have been amended to contain new matter is bas\ed upon a position that the instant specification, as filed, did not expressly identify SEQ ID NO:1 as the amino acid sequence of a cysteinyl leukotriene receptor.

It was only in response to Appellant's arguments that the claimed invention has utility as a receptor for cysteinyl leukotrienes and the introduction of the limitation "wherein the polypeptide has cysteinyl leukotriene receptor activity" that the issues of whether the instant specification actually asserts that a protein comprising the amino acid sequence presented in SEQ ID NO:1 of the instant application had leukotriene receptor activity and, of equal importance, if the specification identified a specific and substantial utility for that protein based upon such an activity.

First, there was no evidence presented in the instant application, as filed, that a protein comprising the amino acid sequence presented in SEQ ID NO:1 of the instant application had leukotriene receptor activity. Appellant asserts that the specification as filed supports a conclusion that the amino acid sequence presented in SEQ ID NO:1 is the amino acid sequence of a member of the G protein-coupled receptor (GPCR) family and that essentially all of the members of this protein family have ligands. This has never been disputed. The assertion that SEQ ID NO:1 is the amino acid sequence of a

naturally occurring human GPCR and that there exists one or more compounds that function as a natural ligand, and more specifically, as an agonist for that receptor protein has never been questioned by the examiner of record.

However, as explained in the section beginning on page 1 of the instant specification entitled "**BACKGROUND OF THE INVENTION**", members of the GPCR family mediate a variety of dramatically different physiological process in response to an equally varied assortment of ligands. For example, as stated therein, there are GPCRs for the compound dopamine and GPCRs for the compound adrenaline. In fact, it is old and well known in the art that G protein-coupled dopamine receptors and G protein-coupled adrenalin (adrenergic) receptors are very closely related even within this protein family, as are their respective ligands dopamine and adrenaline (epinephrine). However, it is also old and well known in the art that the physiological consequences of activating dopamine receptors by administering L-dopa to an individual are profoundly different from the consequences of activating adrenergic receptors through the administration of adrenaline or methamphetamines. Therefore, simply knowing that a particular protein is a member of the GPCR family does not inherently provide one with a specific and substantial utility for that protein.

It is noted that Appellant has never been required to disclose a ligand for the claimed protein to establish a specific and substantial utility for that protein. Utility for a receptor protein does not necessarily require the identification of a ligand thereto. When a particular protein is disclosed as being expressed in a diseased form of a tissue whereas it is absent from corresponding healthy tissue, or visa versa, that protein has a

specific and substantial utility in a diagnostic application. Further, if there is evidence or sound scientific reasoning provided that reasonably supports a conclusion that the activation or inhibition of the claimed protein would be expected to have a particular effect upon a specific physiological activity or process such as vasoconstriction, smooth muscle relaxation, or heart rate, then the protein has a specific and substantial utility in the identification of agonist and antagonists thereto. The instant rejections have been made and maintained because, even though the instant specification credibly identifies SEQ ID NO:1 as the amino acid sequence of a naturally occurring human G protein-coupled receptor, it does not expressly identify any ligand for that receptor nor does it identify a specific physiological process that one could reasonably associate with that receptor in light of the evidence of record.

Appellant urges that paragraph 0004 and Table 2 on page 81 of the specification indicates that the polypeptide of SEQ ID N0:1 is a G-coupled Protein Receptor for cysteinyl letlkotrienes. No, it does not. As indicated above, the text corresponding to paragraph 0004 of the instant specification, which is the first full paragraph on page 2, states that "GPCRs include receptors for sensory signal mediators (e.g., light and olfactory stimulatory molecules; adenosine, γ-aminobutyric acid (GABA), hepatocyte growth factor, melanocortins, neuropeptide Y, opioid peptides, opsins, somatostatin, tachykinins, vasoactive intestinal polypeptide family, and vasopressin; biogenic amines (e.g., dopamine, epinephrine and norepinephrine, histamine, glutamate (metabotropic effect), acetylcholine (muscarinic effect), and serotonin); chemokines; lipid mediators of inflammation (e.g., prostaglandins and prostanoids, platelet activating factor, and

leukotrienes); and peptide hormones (e.g., bombesin, bradykinin, calcitonin, C5a anaphylatoxin, endothelin, follicle-stimululating hormone (FSH), gonadotropic-releasing hormone (GnRH), neurokinin, and thyrotropin-releasing hormone (TRH), and oxytocin)". This text is absolutely silent with respect to a protein comprising the amino acid sequence presented in SEQ ID NO:1 of the instant application.

The argument that Table 2 on page 81 of the specification constitutes an assertion that SEQ ID NO:1 is the amino acid sequence of a cystienyl leukotriene receptor has been considered in light of the text bridging pages 25 and 26 of the specification, which defines the term "Probability Score", and found unpersuasive. At best, Table 2 teaches that "the nearest Genebank homolog" of SEQ ID NO:1 is the amino acid sequence of a known cystienyl leukotriene receptor and that the observed similarities between SEQ ID NO:1 and that known receptor, which are not disclosed, are not the result of random chance. It is noted that no conclusions are provided with respect to the functions of a receptor protein comprising SEQ ID NO:1.

Further, whereas the specification is silent of the function of a polypeptide comprising SEQ ID NO:1 beyond the assertion that it is a GPCR, the text at the top of page 26 of the instant specification provides an analysis of the data allegedly presented in Tables 2 and 3 with regard to SEQ ID NO:3, which is the only sequence from Table 2 whose function is discussed therein. That text observes that the closest Genebank homologs to SEQ ID NO:3 are known serotonin (5HT) receptors. However, the specification does not assed that SEQ ID NO:3 is the amino acid sequence of a serotonin receptor. Instead, it asserts that SEQ ID NO:3 is the amino acid sequence of

a "G-protein coupled receptor" that "acts as a receptor for serotonin, another neurotransmitter molecule, or another biogenic amine". This hardly rises to the level of an assertion that a specific sequence presented in Table 2 has the same function as the closest known Genebank homolog and certainly does not constitute a disclosure of a specific and substantial utility for a protein comprising any one of those sequences.

These rejections should be affirmed because the instant specification failed to disclose a specific and substantial utility for the claimed polypeptide. Not only does it fail to expressly assert that SEQ ID NO:1 is the amino acid sequence of a cystienyl leukotriene receptor, it fails to attribute any particular physiological relevance to the activation or inhibition of that protein by an agonist or antagonist thereto. Therefore, even if the instant specification had expressly asserted that that SEQ ID NO:1 is the amino acid sequence of a cystienyl leukotriene receptor, it fails to disclose how this information supports a specific and substantial utility for the claimed polypeptide. An assertion that a polypeptide is a cystienyl leukotriene receptor is not an asserted utility. It is simply the disclosure of a property that is inherent to a compound. See Example 12 of the "REVISED INTERIM UTILITY GUIDELINES TRAINING MATERIALS", which explains why an isolated nucleic acid encoding an receptor that "binds protein X" lacks utility in the absence of the disclosure of a specific role for either the nucleic acid or protein in a known disease or disorder or a physiological process which one would wish to manipulate for clinical effect. See REVISED INTERIM UTILITY GUIDELINES TRAINING MATERIALS (http://ptoweb.uspto.gov/patents/filecab/documents/Utility.pdf - 188.0KB, 28 Feb. 2000)

Appellant has presented the Heise et al. publication,(J. BIOL. CHEM. (September 2000), Vol. 275, No. 39, pp 30531-30536, as evidence that, subsequent to the filing of the instant application, the claimed polypeptide has been shown to function as cysteinyl leukotriene receptor. The fact that SEQ ID NO:1 has subsequently been found to correspond to the amino acid sequence of a cysteinyl leukotriene receptor does not obviate the above rejections because the instant specification did not disclose this critical information. An invention must be patentable at the time that an application is filed. Applicant may not rely upon discoveries made by themselves or others subsequent to the filiing of a patent application to complete the invention claimed therein. In the decision *In re Lundberg*, 117 USPQ 190, 1958, the CCPA held that "advantages which are not disclosed in application cannot be urged as basis for allowing claims". Further, It is a matter of law that an invention must have a specific and substantial utility "in currently available form", which precludes the need for further research, if that research is needed to establish or reasonably confirm a utility for the claimed invention (*Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966)),.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

John D. Ulm

Conferees:

JOHN ULM
PRIMARY EXAMINER
GROUP 1800

JANET L. ANDRES
SUPERVISORY PATENT EXAMINER

BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600